REMARKS

Applicants respectfully request entry of the Amendment and reconsideration of the claims. Claim 2 has been cancelled. Claim 4 has been amended to correct a typographic error. Claim 5 has been amended to correct the claim dependency due to the incorporation of claim 2 into claim 1. No new matter has been added through the amendment. Support for the amendment to claim 1 can be found throughout the specification, including at page 24, line 3. Support for the amendment to claim 4 can be found throughout the specification, including at page 2, line 25. Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103.

Rejection Under 35 U.S.C. §103

Claims 1-6 are rejected under 35 U.S.C. §103(a) for alleged obviousness. The Examiner asserts that claims 1-6 are unpatentable over Skochii et al., Likars'ka sprava/Ministerstvo okhorony zdorov'ia Ukrainy, (Sept.-Dec., 1994) (9-12)109-11 (abstract). Applicants respectfully traverse the rejection.

To establish a *prima facie* case of obviousness, three criteria must be met--a suggestion or motivation to combine references, a reasonable expectation of success, and the prior art reference teaches or suggests all the claim limitations. MPEP §2143; *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). Applicants respectfully assert that the Examiner has not established a *prima facie* case of obviousness since:

(1) Skochii et al. do not provide a reasonable expectation of success that pyridoxal-5'-phosphate alone, and in the treatment regimen claimed, would be successful in treating cerebral ischemia and ischemic stroke; and

(2) Skochii et al. do not teach or suggest all of the claim limitations.

(1) **No reasonable expectation of success**

Skochii et al. teach the administration of a regimen of tocopherol acetate (vitamin E), ascorbic acid (vitamin C), pyridoxal phosphate, and glutamic acid. Skochii et al. do not teach that any of the individual components of the regimen will be successful in treating cerebral ischemia and ischemic stroke. According to Skochii et al., it is this cocktail that produces the

reduction in LPO concentration. At page 2, 3rd full paragraph ("In 12 patients..."), Skochii et al. describe the role of each of the different components. If each component of the regimen has a role, then there is no reasonable expectation of success that the individual component of pyridoxal-5'-phosphate would treat cerebral ischemia and ischemic stroke. As such, Applicants respectfully assert that the Examiner has not established a *prima facie* case of obviousness.

(2) No teaching or suggestion of all of the claim limitations

Skochii et al. teach an extremely high dose of pyridoxal phosphate: 1.5 grams of oral dosages, three times a day plus 2 grams of intramuscular injection once a day (e.g., 6.5 grams of pyridoxal phosphate per day). Claim 1, as currently amended, recites an amount of about 0.5 to 50 mg/kg per day of the mammal's body weight of pyridoxal-5'-phospate. For an average person (75 kg), the upper limit of the therapeutically effective amount equates to about 3.75 grams per day. This amount is well below the 6.5 grams administered by Skochii et al. Thus, Applicants respectfully submit that the dosages recited in claim 1 are not taught or suggested by Skochii et al.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

CONCLUSION

In view of the above amendments and remarks, Applicants respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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